



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,136	01/12/2001	Stephen Nuss	990356.ORI	2264

23595 7590 02/13/2002

NIKOLAI MERSEREAU & DIETZ, P.A.
820 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 55402

EXAMINER

WINGOOD, PAMELA LYNN

ART UNIT	PAPER NUMBER
----------	--------------

3736

3

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,136

Applicant(s)

Nuss

Examiner

Pamela Wingood

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other:

Art Unit: 3736

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On Page 1 at line 18, after “though” delete “a”.

On Page 2, at line 21, after “physical” delete “.”.

On Page 6, at line 17, after “which” delete “is”.

On Page 7, at line 3, insert a “.” after weight.

On Page 8 at lines 2 and 4, respectively, delete “it’s” and insert “its”.

On Page 8, at line 7, change “staeeel” to “steel”.

On Page 8 at line 9, change “is” to “it”.

On Page 9, at line 15, insert a “.” after “kinking”.

On Page 9, at line 20, delete “it” and insert “is”.

On Page 10, at line 8, delete extra periods.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3736

3. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 claim a method of making or manufacturing the guidewire and the preamble of claim 9 should be changed accordingly. In Claim 9 at line 5, there should be a semicolon followed by the word "and" before the end of the line.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fagan et al.

Fagan discloses a guidewire of a length of titanium molybdenum alloy wire (Col. 11, lns. 47-60) having a proximal end tapering to a smaller diameter and hence softer distal end (Fig.10), a coil around the distal end and a rounded distal weld (63'). Furthermore, the wire of the TiMo alloy is ground to reduce the diameter (Col 11, lns. 37-42). In Fig. 10, the core wire is inserted into the coil at the distal end and the distal weld is produced (Col 15, lns. 27-37). Regarding Claims 2, 3, and 10 the core of (Fig. 10) shows a tapered tip which would necessarily be more flexible or softer than a thicker region that is more proximal despite the hardening process for

Art Unit: 3736

Claim 10 (Col. 15, lns. 57-61); although typically, tapering produces increased distal flexibility (Col. 8, lns. 2-6). Regarding claims 11, the heat treating process of (Col. 15, lns. 45-61) provides of gradient of softness that is a decreased gradient of softness, not of increased softness, that acts to enhance the hardness of the distal end of the device.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fagan et al. in view of Sepetka et al..

Fagan et al. discloses the limitations above but does not disclose a guidewire having a distal end with a coil touching the distal end.

Sepetka et al. discloses a guidewire having the coil wrapped around and touching the core in an analogous art for the purpose of reducing its friction during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Fagan et al. as shown by Sepetka et al. because the coil directly on the surface of the core would provide as small a diameter as possible thus preventing friction and impingement on the surrounding matter.

Art Unit: 3736

PrDETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On Page 1 at line 18, after "though" delete "a".

On Page 2, at line 21, after "physical" delete ".".

On Page 6, at line 17, after "which" delete "is".

On Page 7, at line 3, insert a "." after weight.

On Page 8 at lines 2 and 4, respectively, delete "it's" and insert "its".

On Page 8, at line 7, change "staeel" to "steel".

On Page 8 at line 9, change "is" to "it".

On Page 9, at line 15, insert a "." after "kinking".

On Page 9, at line 20, delete "it" and insert "is".

On Page 10, at line 8, delete extra periods.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3736

3. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 claim a method of making or manufacturing the guidewire and the preamble of claim 9 should be changed accordingly. In Claim 9 at line 5, there should be a semicolon followed by the word "and" before the end of the line.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fagan et al.

Fagan discloses a guidewire of a length of titanium molybdenum alloy wire (Col. 11, lns. 47-60) having a proximal end tapering to a smaller diameter and hence softer distal end (Fig. 10), a coil around the distal end and a rounded distal weld (63'). Furthermore, the wire of the TiMo alloy is ground to reduce the diameter (Col 11, lns. 37-42). In Fig. 10, the core wire is inserted into the coil at the distal end and the distal weld is produced (Col 15, lns. 27-37). Regarding Claims 2, 3, and 10 the core of (Fig. 10) shows a tapered tip which would necessarily be more flexible or softer than a thicker region that is more proximal despite the hardening process for

Art Unit: 3736

Claim 10 (Col. 15, lns. 57-61); although typically, tapering produces increased distal flexibility (Col. 8, lns. 2-6). Regarding claims 11, the heat treating process of (Col. 15, lns. 45-61) provides of gradient of softness that is a decreased gradient of softness, not of increased softness, that acts to enhance the hardness of the distal end of the device.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fagan et al. in view of Sepetka et al..

Fagan et al. discloses the limitations above but does not disclose a guidewire having a distal end with a coil touching the distal end.

Sepetka et al. discloses a guidewire having the coil wrapped around and touching the core in an analogous art for the purpose of reducing its friction during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Fagan et al. as shown by Sepetka et al. because the coil directly on the surface of the core would provide as small a diameter as possible thus preventing friction and impingement on the surrounding matter.

Art Unit: 3736

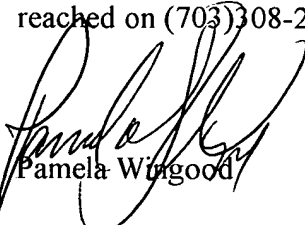
Allowable Subject Matter

8. Claims 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: Prior art of record did not suggest or disclose a guidewire of the claimed percentages by weight.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. Chandrasekaran (5,673,707) teaches the use of a rounded tip on the distal tip of a guidewire to for facilitating placement of the guidewire without puncturing the vessel.

Any questions regarding this application can be addressed to Pamela Wingood who can be reached on (703) 308-2676 on Monday-Thursdays and alternate Fridays from 7:30-5:00PM.



Pamela Wingood

Patent Examiner

February 10, 2002